

Silesian Park of Medical Technology Kardio-Med Silesia Sp. z o. o.  
M. Curie-Skłodowskiej Street 10c,  
41-800 Zabrze

No reg. 15/Z/24

Zabrze, 09.09.2024

## TERMS AND CONDITIONS OF THE CONTRACT

Procurement procedure for  
**„Contractor selection for contract manufacturing of a GMP-standard investigational medicinal product based on liposome technology for use in a Phase I clinical trial, with the required documentation”**  
within

Project entitled commercial clinical trial project - development of innovative therapeutic solutions using RNA technology

The study is financed by the state budget from the Medical Research Agency, project number 2021 / ABM / 05/00002

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## I. ORDERING AUTHORITY

Silesian Park of Medical Technology Kardio-Med Silesia Sp. z o. o.

M. Curie-Skłodowskiej Street 10c, 41-800 Zabrze

Tel: 032/ 7050305

Website: [www.kmptm.pl](http://www.kmptm.pl)

E-mail address for contact with the Contracting Authority: [postepowania@kmptm.pl](mailto:postepowania@kmptm.pl)

## II. DESCRIPTION OF THE SUBJECT MATTER OF THE CONTRACT

1. The subject of this procedure is the contract manufacturing of an investigational medicinal product in GMP standard, based on liposome technology for use in the Phase I clinical trial, in the amount of 3000 ml (delivered in three batches - 3 x 1000 ml, portioned in packages of 5 ml each) according to Annex No. 4 to the ToR, and the transfer of the necessary documents required for the drug registration process.
2. Specification of the main scope of the subject of the contract:
  - a) Provision by the Contractor of the necessary documents certifying the Contractor's manufacturing capabilities, including:
    - an appropriate authorization for the manufacture of a medicinal product, as referred to in Article 38 (1) et seq. of the Act of September 6, 2001. - Pharmaceutical Law (Journal of Laws of 2021, item 1977, as amended), issued by the Chief Pharmaceutical Inspector,
    - certificate of fulfillment of the requirements of Good Manufacturing Practice (GMP certificate), Documentation of the General Place of Business (DGM), prepared in accordance with Annex No. 4 of the Regulation of the Minister of Health of November 9, 2015 on Good Manufacturing Practice (Journal of Laws of 2022, item 1273, as amended),
    - after signing the contract with the Contractor, it is required to provide documents confirming the approval for the manufacture of the Investigational Medicinal Product.
  - b) Manufacture of 3,000 ml of the Investigational Medicinal Product, within 3 batches (1 batch = 1,000 ml of product portioned into 5 ml packages), for administration in the Phase I clinical trial, based on the specifications and requirements of the Employer, in accordance with the developed technological process, including all the steps required by the process, including:
    - procurement of reagents and qualification of suppliers,
    - quality control of intermediate and final products within each batch,
    - development of analytical methods for assays that will not be transferred through technology transfer from the Contracting Authority (in accordance with the table provided upon signing of the Non-Disclosure Agreement, which also includes information on the responsibilities of the Contracting Authority and the Contractor),
    - release of each batch by a Qualified Person,
    - the sterilization process,
    - packaging, labeling and blanking process (in accordance with Regulation 536/2014). A sample of all labels will be sent to the Contractor within 14 days from the date of transfer of the authorization to the Contracting Authority referred to in § 1.2.4 of the Agreement.
    - and all required accompanying processes
  - c) Development and delivery of the necessary documentation for each batch of manufactured investigational medicinal product, including: batch release certificates, certificates of analysis, quality control protocols, and all required documents necessary for the submission of documentation for the authorization of the Phase I clinical trial and the administration of manufactured medicinal products in the Phase I clinical trial
  - d) Purchase of saline manufactured to GMP standard and its proper batching (into 5 ml packs), labeling (according to the submitted label template) and blinding

- e) Delivery a certificate issued by a Qualified Person certifying that the manufacture of the product in question complies with GMPs
- f) preparation of documentation in accordance with Regulation 536/2014, including IMPD (within the scope of the Contractor's responsibilities)
- g) Perform stability studies:
  - within 3 months from the date of manufacture of the Product and submission of documentation confirming the performance of the analyses
  - within 6 months from the date of manufacture of the Product and submission of documentation confirming the performance of the analyses-w terminie 6 miesięcy od dnia wytworzenia Produktu oraz przekazanie dokumentacji potwierdzającej wykonanie analiz.

3. Packaging of the subject of the order (investigational medicinal product and NaCl):

- a) 5 ml portions of the Product (of the concentration specified in the specifications provided upon signing of the Confidentiality Agreement) - portioned in 5 ml opaque sterile polyethylene bottles, tested for compliance with the requirements of the European Pharmacopoeia, in the quantity of 600 units.
- b) Saline (NaCl) purchased in GMP-standard bulk packaging - portioned in 5 ml opaque sterile polyethylene bottles (identical to the Product), tested for compliance with the requirements of the European Pharmacopoeia, in a quantity of 200 pcs.

Method of packaging:

- a) 5 ml portions of the Product (labeled), each packed in a separate outer master carton (labeled), which should be secured with a seal sticker. The above should be packed collectively in 10 pieces in a bulk box with the appropriate label and information about the Product No. and the number of pieces in the package.
- b) 5 ml portions of saline (labeled), each packaged in a separate outer master carton (labeled), which should be secured with a seal sticker. The above should be packaged collectively in 10 pieces in a bulk box with the appropriate label and information about the number of saline and the number of pieces in the package

Place of performance of the subject matter of the Agreement: the Contractor's headquarters/laboratory with transportation to the Contracting Authority's premises, if the Contracting Authority does not specify another place of delivery.

4. CPV CODE:

- 33600000-6 Pharmaceutical products
- 33690000-3 Various medicinal products
- 73110000-6 Research services

5. The Contracting Authority shall provide the potential Contractor with the specifications necessary for the preparation of the bid, i.e. names and estimated quantities/numbers of ingredients, catalog number of saline (NaCl) required for purchase produced in accordance with GMP standard, which are necessary for the manufacture of the medicinal product, along with information on the length of the peptide sequence (the amino acid sequence, due to company secrecy, will be provided only to the selected, through this procedure to the Manufacturer after the signing of the manufacturing Agreement) and the properties of the manufactured preparation, information on the possible inspection carried out at the Contractor within the framework of the Contracting Authority's Quality System, however, due to the need to protect corporate confidentiality, reserves the right to provide it after signing a confidentiality agreement with the potential Contractor. A model Agreement can be found in Appendix 7 to the Tender Request.

The Agreement, signed with an electronic signature, should be sent to: [postepowania@kmptm.pl](mailto:postepowania@kmptm.pl), and signed by hand to the address of the company's headquarters, i.e. Silesian Park of Medical Technologies Kardio-Med Silesia sp. z o.o., 10C Marii Curie-Skłodowskiej Street, 41-800 Zabrze, no later than 7 working days before the deadline for submission of tenders.

The non-disclosure agreement should be completed and signed by a person authorized to represent

the Contractor. Responses to questions with relevant documents will be made available by the Contracting Authority within three working days:

- 1) from the signing of the Confidentiality Agreement by both Parties - in case it is signed using an electronic signature;
  - 2) from providing the Contractor with a scan of the Confidentiality Agreement signed by both Parties - in case it will be signed by hand, whereby the Contracting Authority agrees to forward one copy of the signed Confidentiality Agreement to the Contractor at the Contractor's address.
6. The contract is financed under the ongoing commercial clinical trial project - development of innovative therapeutic solutions using RNA technology financed from the state budget from the Medical Research Agency, Project number 2021/ABM/05/00002.
7. The Contracting Authority may cancel the procedure if the funds from the above-mentioned programs that the Contracting Authority intended to finance all or part of the contract were not awarded to it.

### III. DESCRIPTION OF TENDER PREPARATION

1. To be evaluated, a tender should meet the requirements of these Terms of Reference.
2. The tender submitted by the Contractor should be made in writing.
3. The tender shall be constituted by Appendices: no. 1, no. 2, no. 4, no. 5, no. 6, no. 6a, no. 7 and other documents and declarations of will signed by the Contractor as required by the TERMS AND CONDITIONS OF THE CONTRACT.
4. The Contractor shall fulfill all conditions required in point V.
5. A tender shall be signed by a person authorized to represent the Contractor, which has to result from the documents attached to the tender.
6. The offer submitted by the Contractor should be made in Polish or English.
7. The all pages of the tender should be connected in a permanent manner that prevents them from sliding out, numbered and each sheet signed /in accordance with point 5/.
8. Any corrections or changes to the offer should be signed personally by the person signing the tender /according to point 5/.
9. The Contracting Authority shall correct obvious calculation errors, taking into account the calculation consequences of the corrections made. By obvious calculation errors the Contracting Authority understands a defective result of an arithmetic operation assuming that the number of units of measurement and net unit price are correctly stated.
10. If the tender price is given with a discrepancy in words and numbers or different prices are given in different parts of the tender, it shall be assumed that the correct entry is the one that corresponds to the price calculation.
11. The Contracting Authority shall correct obvious clerical errors in the tender.
12. The Contracting Authority shall correct other errors in the tender which consist in non-compliance of the tender with the Terms of Reference, but which do not result in significant changes in the contents of the Tender - immediately notifying the Contractor whose Tender has been corrected.
13. Each Contractor can submit only one tender.
14. The tender shall be put in a sealed envelope which guarantees confidentiality of its content.
15. The envelope should be addressed to:

**Silesian Park of Medical Technology Kardio-Med Silesia Sp. z o. o.  
M. Curie-Skłodowskiej Street 10c,  
41-800 Zabrze**

and marked with the following inscription:

**Offer for the proceedings to award a contract for  
„Contractor selection for contract manufacturing of a GMP-standard investigational medicinal  
product based on liposome technology for use in a Phase I clinical trial, with the required  
documentation” (15/Z/24)**  
within

**commercial clinical trial project - development of innovative therapeutic solutions using  
RNA technology**

16. The envelope must also be marked with the name and address of the Contractor.
17. The Contracting Authority shall reject a tender if:
  - 1) its content or form of submission does not correspond to the contents of the Terms of Reference (subject to Chapter III, points 8-10);
  - 2) within 3 days from the date of delivery of the notice a Contractor has not agreed to correct the error referred to in item 11.
  - 3) it contains errors in price calculation, subject to item 8;
  - 4) the Contractor failed to submit explanations and/or supplemented tender deficiencies within the specified deadline;
  - 5) the tender was submitted by a Contractor with respect to whom liquidation proceedings have been opened or the Contractor has been deleted from the proper register
  - 6) it was submitted after the deadline for submission of Tenders;
  - 7) the Tender was submitted by a Contractor:
    - a) having capital ties with the Contracting Authority<sup>1</sup>
    - b) the Contractor is personally related to the Contracting Authority<sup>2</sup>
    - c) against whom there are grounds for exclusion from the proceeding under Article 7 (1) of the Act of April 13, 2022 on special solutions to prevent support for aggression against Ukraine and to protect national security (Journal of Laws, item 835
  - 8) was submitted by a Contractor who does not meet the conditions for participation in the proceedings);Oferta złożona po terminie składania ofert zostanie zwrócona Wykonawcy.
18. An offer submitted after the deadline for submission of tenders will be returned to the Contractor.
19. The procedure is open to the public. The Contractor may reserve in the Tender the information which constitutes the CONFIDENTIALITY OF THE COMPANY (according to art. 11 item 4 of the Act on Fighting Unfair Competition). For this purpose, he/she shall:
  - the names of the documents in the offer that constitute the proprietary information should be highlighted graphically in the list of Appendices,
  - documents containing proprietary information should be bound and put in a separate non-transparent cover, inside the cover there should be a list of contents signed by the Contractor,
  - the Contracting Authority shall not be responsible for the consequences of failure to properly secure the above information.

#### **IV . DESCRIPTION OF TENDER PRICE CALCULATION METHOD**

1. Tender, the Contractor shall offer a complete, unambiguous and final price, which covers all the expected costs of performance of the subject matter of the contract.
2. The tender price shall be expressed in Polish zloty to two decimal places.
3. The price expressed in a foreign currency will be converted according to the average exchange rate of the National Bank of Poland on the day of submitting offers.
4. Rates and prices quoted by the Contractor in the tender will not be subject to adjustment during the execution of the contract, except in cases listed in the material provisions of the contract.
5. When calculating the price, it is assumed that the gross value is the net price plus VAT.

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<sup>1</sup> <sup>2</sup>Capital or personal links shall mean mutual links between a beneficiary or persons authorised to incur liabilities on behalf of the beneficiary or persons performing activities related to the execution of the procedure for selecting the contractor and a contractor, consisting in particular in

a) participation in the company as a partner in a civil partnership or partnership,

b) holding at least 10% of shares or stocks, unless a lower threshold results from legal provisions or has been defined by MA OP,

c) being a member of a supervisory or managing body, proxy or attorney,

d) being married, in the relation of kinship or affinity in direct line, kinship of the second degree or affinity of the second degree in side line, or in the relation of adoption, custody or guardianship.

## V. TERMS OF PARTICIPATION IN THE PROCEEDINGS

1. The contract may be competed for by the Contractors who submitted a statement according to the specimen in Appendix no. 2 i.e. confirming that:
  - 1) They have the necessary knowledge and experience necessary for the execution of the contract. (In accordance with point. 2 of this chapter).
  - 2) They have at their disposal adequate technical potential (in accordance with point 2 of this chapter) and infrastructure and personnel, capable of performing the contract, meeting the requirements described in Appendix 5, 6 and 6a
  - 3) They are in an economic and financial condition allowing them to complete the contract.
  - 4) A Tender submitted by a Contractor shall not be rejected on the basis of the Provisions III of art. 17.5),17.7).
  - 5) They have an appropriate authorization for the manufacture of investigational medicinal products, as defined in Article 38 (2) of the Act of September 6, 2001. - Pharmaceutical Law (Journal of Laws of 2021, item 1977, as amended), issued by the Chief Pharmaceutical Inspector and a certificate of compliance with the requirements of Good Manufacturing Practice (GMP certificate),
  - 6) They are fully aware of any problems with the medicinal product or work that may pose a risk to its premises, equipment, personnel and other materials and other medicinal products.
2. The Contracting Authority specifies the following condition for participation in the proceedings regarding knowledge, experience and technical or professional capacity in terms of the Contractor's experience (Appendix 5):

The Contracting Authority will consider the condition as fulfilled if the Contractor demonstrates that in the last 3 years before the deadline for submission of tenders, and if the period of activity is shorter - in this period, has carried out at least three realizations consisting in: manufacturing of medicinal products in liposome manufacturing technology in GMP standard and/or realization of medicinal products in sterile or non-sterile liquid form with a total value of at least PLN 1 million net. The condition is considered fulfilled if the Contractor confirms the implementation with relevant documents (Invoices, references or other supporting documents with a description of the subject of the contract). In the event that the above were not carried out on behalf of an external entity, the Contractor should provide documents confirming the manufacture of products for their own use and/or marketing.

3. In accordance with the Ordinance of the Minister of Health dated November 9, 2015 on the requirements of Good Manufacturing Practice, the Contractor may outsource part of the activities to a third party, with the proviso that this is not possible without prior evaluation and approval of the arrangements with the Purchaser. The arrangements between the Contractor and the third party must ensure that information and knowledge, also derived from the third party's evaluation, is available as with the Contractor. The Contractor shall ensure that a Non-Disclosure Agreement is signed with the third party on the confidentiality of the information provided.
4. The evaluation of the fulfillment of the conditions for participation in the proceedings will be based on the assessment of whether the attached document confirms the fulfillment of the condition for participation in the procurement proceedings or not.

## VI. DOCUMENTS REQUIRED FROM CONTRACTORS

1. The Contracting Authority requires submission with the offer of the following documents:
  - 1) A completed, signed by the person(s) authorized to represent the Contractor tender form constituting (**Appendix no. 1**);
  - 2) Up-to-date copy from the appropriate register or from the central register and information on business activity, issued not earlier than 6 months before the deadline for submission of tenders
  - 3) Contractor's declaration/s (**Appendix no. 2**);

- 4) Price Form completed, signed by a person authorized to represent the Contractor (**Appendix no. 4**);
  - 5) List of realized realizations in accordance with Chapter V, point 2, to the extent necessary to demonstrate the fulfillment of the condition of knowledge, experience and technical or professional capacity in terms of experience of the Economic Operator, made in the last three years before the deadline for submission of tenders in the proceedings, specifying their type and value, date and entities for which the supplies or services were made or performed, and attaching a document confirming that the supplies were duly made, constituting (**Appendix No. 5**);
  - 6) A list of the personnel who will be directly involved in the execution of the contract, along with documentation, confirming the education, qualifications and seniority of the staff member in the position (**Appendix no. 6 and 6a**);
  - 7) Appropriate authorization for the manufacture of medicinal products, as defined by Article 38 (2) of the Act of September 6, 2001. - Pharmaceutical Law (Journal of Laws of 2021, item 1977, as amended), issued by the Chief Pharmaceutical Inspector;
  - 8) Certificate of compliance with the requirements of Good Manufacturing Practice (GMP certificate);
  - 9) Documentation of the General Place of Business (DGM), prepared in accordance with Annex No. 4 of the Regulation of the Minister of Health of November 9, 2015 on Good Manufacturing Practice (Journal of Laws of 2022, item 1273, as amended).
2. The Contracting Authority requires the submission of Appropriate authorization for the manufacture of investigational medicinal products, as defined in Article 38 (2) of the Act of September 6, 2001. - Pharmaceutical Law (Journal of Laws of 2021, item 1977, as amended), issued by the Chief Pharmaceutical Inspector - a document required to be delivered after signing of the Agreement between the Contracting Authority and the Contractor within 30 days from the date of signing the Agreement.
  3. The Contracting Authority shall request the Contractor to clarify ambiguities in the Tender submitted and/or to supplement the Tender by the deadline specified by the Contracting Authority. Any clarifications and additions to the tender cannot lead to a change in the tender price, subject to the provisions of Chapter III, items 8-9. The supplemented documents must confirm the conditions specified in the TERMS AND CONDITIONS OF THE CONTRACT as at the date for submission of tenders.
  4. If the Contractor encloses a copy of a document as an appendix to the tender, such copy shall be certified to be a true copy of the original by a person authorized to represent the Contractor. The certification by the Contractor shall bear a name stamp and a signature of an authorized person, a date and the inscription "certified to be a true copy of the original". If the photocopy is illegible, the Contracting Authority shall call upon the Contractor to produce the original document for comparison with the illegible copy.

## VII. CRITERIA FOR EVALUATION OF TENDERS

When selecting and evaluating the submitted tenders, the Contracting Authority shall be guided by the following criteria:

The lowest price

**The price criterion** will be considered on the basis of the price quoted by the Contractor in the tender form.

The Contracting Authority will consider the most advantageous tender which will obtain the highest number of points for the criteria adopted for the evaluation of tenders.

## VIII. CONTRACT COMPLETION DATE

Contract completion date:

The agreement is executed for a period of 12 months from the date of its conclusion, with implementation in the following stages:

- 1) until 30 days from the signing of the Agreement - transfer of the manufacturing authorization for the investigational drug product to the Contracting Authority;
- 2) until 15.01.2025 - transfer / development of test methods for release of starting materials, packaging, transfer of manufacturing process with process validation, cleaning validation;
- 3) until 28.02.2025. - manufacture of three batches of the Product and transfer of documentation confirming the manufacture of three batches of the Product;
- 4) after three months from the date of manufacture - performance of stability tests under accelerated conditions in accordance with the ICH Q1A(R2) standard and submission of documents of the analyses performed (until 31.05.2025).
- 5) after six months from the date of manufacture - to perform stability tests under accelerated conditions in accordance with ICH Q1A(R2) standard, transfer documents from the analyses performed, and transfer three batches of the Product and saline (until 31.08.2025).

## IX. PLACE AND DEADLINE FOR SUBMITTING TENDERS

1. Tenders should be submitted at the seat of the Silesian Park of Medical Technology Kardio-Med Silesia Ltd., 10c M. C. Skłodowskiej Street, 41-800 Zabrze.
2. The deadline for submission of tenders is **11.10.2024 at 10.00 a.m.**
3. Tenders submitted after this deadline will be immediately returned to the Contractor.
4. If a tender is received by the Contracting Authority by mail or other means (e.g. courier service), the deadline for submission of a tender shall be the date of its delivery to the Contracting Authority and not the date of e.g. sending the tender by registered mail or placing an order for delivery by courier service.
5. The Contractor shall bear all costs related to preparation and submission of a tender.
6. The Contractor may modify or withdraw a submitted tender if a written notification of such modification or withdrawal is submitted to the Contracting Authority prior to the deadline for submission of tenders.
7. A notification of modification or withdrawal of a tender by a Contractor should be made in writing and marked respectively: "Modification" or "Withdrawal".
8. No tender may be modified or withdrawn after the deadline for submission of Tenders, subject to Chapter III point 11 of the TERMS AND CONDITIONS OF THE CONTRACT.

## X. METHOD OF COMMUNICATION

1. The Contractor may ask for clarification of the contents of the TERMS AND CONDITIONS OF THE CONTRACT in writing or electronically ([postepowania@kmptm.pl](mailto:postepowania@kmptm.pl)).
2. The Contracting Authority shall provide clarifications immediately.
3. If the explanations provided lead to changes in the TERMS AND CONDITIONS OF THE CONTRACT, the Contracting Authority shall extend the deadline for submission of tenders by the time needed to introduce changes to the procedure documentation, giving the date and scope of such changes.
4. The Contracting Authority may also make changes to the Terms of Reference on their own and extend the deadline for submission of tenders by the time necessary to introduce changes to the tender documentation, providing the date and scope of such changes.
5. The Contracting Authority shall communicate with contractors by e-mail or in writing.

## XI. TENDER VALIDITY PERIOD

1. A Contractor shall remain bound by a tender for 90 days.
2. Tender validity period shall begin on the expiry of the deadline for submission of tenders.
3. The Contracting Authority may request the Contractor to extend the tender binding period by no more than 60 days.
4. The Contractor may himself extend the tender binding period.

## **XII. OPENING, EVALUATION OF TENDERS, SELECTION OF THE MOST ADVANTAGEOUS TENDER, CANCELLATION OF THE PROCEDURE**

1. Tenders will be opened on **11.10.2024 at 10.15 a.m.** at Contracting Authority's seat at M. C. Skłodowskiej Street 10c in Zabrze.
2. The opening of tenders is public.
3. **Persons willing to participate in the opening of the tenders will inform the Contracting Authority about this fact at least 24 hours in advance.**
4. During tender opening the amount which the Contracting Authority intends to allocate to the contract, the names and addresses of Contractors and the prices of Their tenders shall be announced.
5. If an Contractor did not attend the tender opening, the Contracting Authority shall send, upon written request, information containing the names and addresses of contractors whose tenders were opened and the prices of those tenders.
6. Evaluation, comparison and selection of the most advantageous final tender shall be performed by a committee appointed by the Contracting Authority (in the proceedings- in which it is appointed).
7. The Contracting Authority may first evaluate tenders and then examine whether the contractor whose tender was evaluated as the most advantageous meets the conditions for participation in the procedure.
8. Selection of the most advantageous tender/cancellation of the procedure shall be subject to approval by the Management Board.
9. If the price of the most advantageous tender is higher than the amount that the Contracting Authority can allocate to the contract, the Contracting Authority may cancel the procedure.
10. If no tender has been submitted in the proceeding or all tenders submitted are subject to rejection the Contracting Authority shall cancel the proceeding.
11. Information
  - about the selection of the most advantageous tender / cancellation of the procedure,
  - Contractors whose tenders have been rejected the Contracting Authority shall send immediately after the selection of the most advantageous tender to the participants in the proceedings.
12. The announcement of the result shall also be posted on the Contracting Authority's website.

## **XIII. PERSONS AUTHORIZED TO CONTACT THE CONTRACTORS**

Authorized to contact Contractors are:

[postepowania@kmptm.pl](mailto:postepowania@kmptm.pl) / [a.bochenek@kmptm.pl](mailto:a.bochenek@kmptm.pl)

## **XIV. ISSUES RELATED TO THE CONTRACT**

1. Essential provisions contained in the contract and foreseen possibilities and conditions of amending it are included in Appendix no. 3.
2. The Contractor shall be obliged to come to the Contracting Authority's seat within 3 working days (Mon-Fri from 8.00 a.m. to 4.00 p.m.) from the date of the notification of selecting the winning tender in order to sign the contract (if requested to do so by the Contracting Authority).
3. If the selected Contractor fails to appear according to item 2, the Contracting Authority shall have the right to sign the contract with the Contractor whose tender is next in order according to the tender evaluation criteria.

4. If the Contractor joint tender is found to be the most advantageous, before the conclusion of the public procurement contract they shall, at the request of the Awarding Entity, submit the contract governing the cooperation of these Contractors, containing at least the following provisions:
- establishing an agreement at least for the period not shorter than the duration of the public procurement contract,
  - indication of the Proxy as the entity making the settlements,
  - joint and several liability for the contract,
  - prohibition to change Partners (Contractors) jointly realizing a public contract during the term of the public contract.

In matters not regulated by these documents, the following shall apply:

- Act of April 23, 1964 Civil Code (Journal of Laws of 2023, item 1610, as amended);
- Contracting Authority's Procurement Regulations available at <http://www.kmptm.pl>

I approve  
**Adam Konka**

**President of the Management Board**  
**Silesian Park of Medical Technology Kardio-Med Silesia Sp. z o. o.**

(stamp of Contractor)

date .....

**TENDER FORM**

In response to the contract award notice for the „**Contractor selection for contract manufacturing of a GMP-standard investigational medicinal product based on liposome technology for use in a Phase I clinical trial, with the required documentation**” (15/Z/24) as part of a commercial clinical trial project - development of innovative therapeutic solutions using RNA technology, we offer the subject of the contract to the extent covered by the Terms of Reference for the price:

**Gross price ..... PLN, VAT rate .....**

**In words, gross price:.....**

1. We hereby that we meet all the requirements contained in the Terms of Reference and accept them without reservation and that we have received all necessary information needed to prepare the tender.
2. We hereby declare that all documents submitted by us are compliant with the current legal and factual state.
3. We hereby declare that we consider ourselves bound by this tender for the time period indicated in the terms of reference.
4. We declare that the draft contract contained in the specification of essential terms of the contract has been accepted by us and in the event of choosing our offer - we declare the readiness to sign the contract on the terms specified in the draft contract, constituting Appendix No. 3 to the TERMS AND CONDITIONS OF THE CONTRACT, at the place and time specified by the contracting authority.
5. I declare that I have the documents allowing the offered subject of the contract to be marketed in the territory of the country (if applicable) and I undertake to deliver them at each request of the Contracting Authority, on the date indicated by him.
6. I declare that we accept the payment schedule indicated in § 3 of the Model Agreement.
7. Our e-mail address for receiving correspondence: .....
8. Czas obowiązywania Umowy:  
The agreement is executed for a period of 12 months from the date of its conclusion, with implementation in the following stages:
  - 1) until 30 days from the signing of the contract – transfer of the manufacturing authorization for the investigational drug product to the Contracting Authority;
  - 2) until 15.01.2025 – transfer / development of test methods for release of starting materials, packaging, transfer of manufacturing process with process validation, cleaning validation;
  - 3) until 28.02.2025 – manufacture of three batches of the Product and transfer of documentation confirming the manufacture of three batches of the Product;
  - 4) after three months from the date of manufacture - performance of stability tests under accelerated conditions in accordance with the ICH Q1A(R2) standard and submission of documents of the analyses performed (until 31.05.2025).
  - 5) after six months from the date of manufacture - to perform stability tests under accelerated conditions in accordance with ICH Q1A(R2) standard, transfer documents from the analyses performed, and transfer three batches of the Product and saline (until 31.08.2025).

The appendices to this tender are:

1. ....
2. ....

- 3. ....
- 4. ....

.....  
*(signature of authorized representative)*

.....  
(Contractor's address stamp)

**STATEMENT**

**I. By submitting a tender I declare that:**

1. I have the necessary knowledge and experience necessary for the execution of the contract.
2. Have at my disposal appropriate technical potential and staff capable of performing the contract
3. I am in an economic and financial condition allowing me to complete the order.
4. I have an appropriate authorization for the manufacture of medicinal products, as defined in Article 38 (2) of the Act of September 6, 2001. - Pharmaceutical Law (Journal of Laws of 2021, item 1977, as amended), issued by the Chief Pharmaceutical Inspector and a certificate of compliance with the requirements of Good Manufacturing Practice (GMP certificate).
5. I am fully aware of any problems with the medicinal product or work that may endanger its premises, equipment, personnel and other materials and other medicinal products. Oferta złożona przez Wykonawcę, którego reprezentuję nie podlega odrzuceniu na podstawie zapisów Rozdziału III pkt. 17.5).
6. I am not related to the Contracting Authority by capital\*
7. I am not personally related to the Contracting Authority\*\*
8. There are no grounds for exclusion of me from the proceedings under Article 7 (1) of the Law of April 13, 2022 on special solutions to prevent support for aggression against Ukraine and to protect national security (Journal of Laws, item 835).

....., date .....

.....  
(signature of the authorized representative)

\*/\*\* Capital or personal links shall mean mutual links between the beneficiary or persons authorised to incur liabilities on behalf of the beneficiary or persons carrying out activities related to the contractor selection procedure on behalf of the beneficiary and a contractor, consisting in particular in

- a) participation in the company as a partner in a civil partnership or partnership,
- b) holding at least 10% of shares or stocks, unless a lower threshold results from legal provisions or has been defined by MA OP,
- c) being a member of a supervisory or managing body, proxy or attorney,
- d) being married, in the relation of kinship or affinity in direct line, kinship of the second degree or affinity of the second degree in side line, or in the relation of adoption, custody or guardianship.



Commercial clinical trial project - development of innovative therapeutic solutions using RNA technology

(Material provisions of the agreement)

**AGREEMENT NO ...../ABM/24**

concluded on ..... 2024 r. in Zabrze<sup>2</sup> between:

**Silesian Park of Medical Technology Kardio-Med Silesia Ltd.**

with headquarters in Zabrze, ul. M. Curie- Skłodowskiej 10c, registered in the Register of Entrepreneurs of the National Court Register kept by the District Court in Gliwice, 10th Commercial Division of the National Court Register under the number KRS 0000396540, NIP 648-276-15-15, REGON 242742607, represented by:

Adam Konka - President of the Management Board

hereinafter referred to as **"the Ordering Party"** or **"the Contracting Authority"**

(in the case of an entrepreneur entered in the National Court Register)

(name) ....., the registered office in..... Street, NIP: ....., REGON: ....., share capital: ..... entered into the Register of Entrepreneurs kept by the District Court ..... under KRS number: ..... , represented by:

.....

(in the case of an entrepreneur entered in CEIDG)

(name and surname) ....., residing in ..... PESEL: ..... an entrepreneur running a business under the name of ..... based in ... .. at ..... Street, NIP: ..... , REGON: ..... ,

referred to in the contract as the **"Contractor"**, hereinafter also referred to separately as the **"Party"** or jointly as **"Parties"**, as follows:

**§ 1.**

**Subject of the Agreement**

1. The subject of the Agreement is the manufacture and delivery by the Contractor of 3. (in words: three) series of the investigational medicinal product (hereinafter referred to as the "Product"), as well as the purchase, batching and labeling of NaCl saline, in accordance with the requirements of Good

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<sup>2</sup> If the Parties sign the agreement with an electronic signature, the date of conclusion will be the date of the last qualified signature by the Parties.

Manufacturing Practice, the specification and technological process developed by the Ordering Party, Appendix No. 4 to the ToR and the offer submitted in response to the procedure No. **15/Z/24**.

2. By one series of the Product is meant 1000 ml of the Product. The tested medicinal product will be delivered to the Ordering Party in three batches - 3 x 1000 ml portioned into packages (polyethylene bottles, opaque, sterile tested for compliance with the European Pharmacopoeia) of 5 ml each. Portioned Product packaged in packs of 10 pieces each, labeled in accordance with Regulation 536/2014 and the sample labels provided by the Purchaser.
3. The Contractor represents that:
  - 1) it has a Quality System in place, including an organizational structure, procedures, processes and resources, as well as the activities necessary to ensure that the active substance will meet the expected specification requirements for its quality and purity. All quality activities are defined and documented;
  - 2) has developed and applies hygiene maintenance programs, in particular, procedures for controlling the health, hygiene and work clothes of employees.
4. In particular, the Contractor shall:
  - 1) provide, within 30 days from the date of signing the Agreement, a manufacturing permit for the investigational medicinal product. The Ordering Party shall have the right to withhold payment of the advance invoice until the Contractor provides the aforementioned permit;
  - 2) purchase, as part of the contractual remuneration, all materials, including reagents, necessary for the manufacture of the Product, having the properties necessary for the manufacture of the Product;
  - 3) manufacture the Product at the Site;
  - 4) to direct only qualified personnel for the execution of the Contract, with practical experience that allows the Product to be manufactured correctly and in accordance with the Ordering Party's needs, including the provision of a Qualified Person with the qualifications referred to in Article 39 paragraph 5 item 2 of the Pharmaceutical Law, whose data will be provided to the Ordering Party;
  - 5) to provide the personnel assigned to the execution of the contract with all equipment and work clothes ensuring safety in the execution of the Contract;
  - 6) prepare documentation in accordance with Regulation 536/2014, including IMPD (within the scope of the Contractor's responsibilities) and submit it simultaneously with the Product series;
  - 7) prepare and deliver to the Ordering Party, together with the Product series to be delivered, the necessary documentation for each Product series, including: batch release certificates, certificates of analysis, quality control protocols, and all required documents necessary for the administration of the manufactured medicinal products in the clinical trial;
  - 8) to allow inspection by the competent inspection authorities and to cooperate with the Contracting Authority in this regard, including to inform the Contracting Authority about the inspection carried out at the Contractor's premises in connection with the manufacturing of the Product;
  - 9) not to make unauthorized changes during the manufacturing process in relation to those arising in particular from the Product specifications and the terms of the Contract, which may adversely affect the quality of the commissioned activities and the quality of the Product;
  - 10) to keep the Ordering Party informed of the occurrence of any irregularities related to the execution of the Contract, with the proviso that failure to inform the Ordering Party in time to prevent the harmful effects resulting from irregularities identified by the Contractor will result in the Contractor being held liable for the damage, regardless of the type of damage;
  - 11) archiving documentation related to the execution of the Contract for a period of at least 5 years from the date of termination of this Contract;
  - 12) packaging of the subject matter of the contract (investigational drug product and NaCl) as follows:

- a) 5 ml portions of the Product (of the concentration specified in the specifications provided upon signing of the Confidentiality Agreement) - portioned in 5 ml opaque sterile polyethylene bottles, tested for compliance with the requirements of the European Pharmacopoeia, in the quantity of 600 pcs.
- b) Saline (NaCl) purchased in GMP-standard bulk packaging - portioned in 5 ml opaque sterile polyethylene bottles (identical to the Product), tested for compliance with the requirements of the European Pharmacopoeia, in a quantity of 200 pcs.

Method of packaging:

- a) 5 ml portions of the Product (labeled), each packed in a separate outer master carton (labeled), which should be secured with a seal sticker. The above should be packed collectively in 10 pieces in a bulk box with the appropriate label and information about the Product No. and the number of pieces in the package.
  - b) 5 ml portions of saline (labeled), each packaged in a separate outer master carton (labeled), which should be secured with a seal sticker. The above should be packaged collectively in 10 pieces in a bulk box with the appropriate label and information about the number of saline and the number of pieces in the package
5. place of performance of the subject of the contract: the Contractor's headquarters/laboratory, with transportation to the Ordering Party's premises, if the Ordering Party does not specify another place of delivery.
  6. All arrangements and changes related to manufacturing activities, including any changes in technical arrangements, must comply with the law and with the requirements of the marketing authorization for the product, if applicable.
  7. If the need for the changes referred to in paragraph 6 is identified, the Contractor shall approach the Contracting Authority, which will decide whether to introduce them or refuse to do so. In the case of introduction of changes, the Contractor's remuneration may be reduced or increased if the Ordering Party confirms that the changes may involve an increase or decrease in the costs incurred by the Contractor in connection with the execution of the Contract. The increase in remuneration due to the introduction of changes will not exceed 10% of the total gross contractual remuneration.
  8. The Ordering Party undertakes to:
    - 1) to provide the Contractor with all necessary information for the manufacture of the Product and preparation of documentation;
    - 2) to send the Contractor samples of all labels within 30 days from the date of sending the authorization referred to in § 1.2.4 of the Agreement.
  9. The Ordering Party shall have the right not to perform the entire Subject of the Contract, and the Contractor shall have no claims against the Ordering Party on this account.
  10. The Contractor undertakes to inform the Contracting Authority of receipt/non-receipt of the permit referred to in § 1.4.2 of the Agreement, no later than 3 days from the date of receipt of information in this regard.
  11. In the case of lack of further possibility of execution of the Contract by persons indicated at the stage of the procurement proceedings, the Contractor shall be obliged to inform the Contracting Authority of this circumstance in each case, provide the data of persons who will be directed to execute the Contract instead, and demonstrate that they have competence and experience not inferior to those replaced. The Contractor shall not be entitled to outsource any activities under this Contract until the approval of the Contracting Authority has been obtained.
  12. The person responsible for the implementation of the Agreement:
    - 1) on the side of the Ordering Party: ....., email: .....
    - 2) on the side of the Contractor: ....., email: .....

The change by the Parties of the persons appointed in accordance with paragraph 3 does not require the conclusion of an annex, but the Parties undertake to inform each other about the changes of the responsible persons.

## **§ 2.**

### **The method of performance of the Agreement**

1. The Agreement will be executed within the timeframe referred to in § 4, by activities performed, i.e.:
  - 1) until 30 days from the signing of the contract – transfer of the manufacturing authorization for the investigational drug product to the Ordering Party;
  - 2) until 15.01.2025 – transfer / development of test methods for release of starting materials, packaging, transfer of manufacturing process with process validation, cleaning validation;
  - 3) until 28.02.2025 – manufacture of three batches of the Product and transfer of documentation confirming the manufacture of three batches of the Product;
  - 4) after three months from the date of manufacture - performance of stability tests under accelerated conditions in accordance with the ICH Q1A(R2) standard and submission of documents of the analyses performed (until 31.05.2025).
  - 5) after six months from the date of manufacture - to perform stability tests under accelerated conditions in accordance with ICH Q1A(R2) standard, transfer documents from the analyses performed, and transfer three batches of the Product and saline (until 31.08.2025).
2. The Contractor shall, on its own and at its own expense, provide for the transportation of the Product, taking into account the conditions of transportation of the Subject of the Contract indicated by the Ordering Party, i.e.
  - 1) transport is possible only through qualified transport service providers that meet the legal regulations - the Law of September 6, 2001. - Pharmaceutical Law and the Regulation of the Minister of Health of March 13, 2015 on the requirements of Good Distribution Practice;
  - 2) ensure that the temperature of the shipment (2-8°C) should be controlled with a validated USB logger, monitoring the temperature during transport and allowing to make a printout of the temperature after receiving the shipment at the destination, displaying an alarm if the temperature is exceeded;
  - 3) prepare and provide transport documentation (including a list of drugs sent in the shipment).
3. The Contractor shall deliver each Product Series and portioned saline in GMP standard to the Contracting Authority's premises (if the Contracting Authority does not specify any other place of delivery). The Contractor undertakes to inform the Contracting Authority about the planned delivery of the Product no later than 4 working days before the planned delivery day. The person authorized to receive the delivery on behalf of the Contracting Authority is .....
4. Confirmation of the completion of each stage of the Contract referred to in paragraph 1 shall be made on the basis of an acceptance protocol, signed by a representative of the Contractor and the Ordering Party, a specimen of which is attached to the Contract.
5. The Contracting Authority shall be entitled to refuse acceptance of a particular stage of the Agreement if it determines that it has not been completed or has been completed incorrectly. In this case, the Contractor shall remain in default until the date of proper execution of the given stage of the Agreement. In this case, the acceptance procedure shall be repeated.

## **§ 3.**

### **Price**

1. For the performance of the Agreement, the Contracting Authority shall pay the Contractor a total remuneration of \_\_\_\_\_ gross, i.e. \_\_\_\_\_ netto (in words: \_\_\_\_\_) + VAT in the amount of \_\_\_\_ % (hereinafter: "Remuneration").
2. Payment of the Contractor's remuneration shall be made in accordance with the following payment schedule:
  - 1) 25% of the Remuneration – on the basis of an advance invoice issued no earlier than 10 days from the date of transfer of the manufacturing permit of the Test Product to the Ordering Party;

- 2) 20% of the Remuneration value – after transfer / development of test methods for release of starting materials, packaging and final product, transfer of manufacturing process with process validation and cleaning validation;
  - 3) 35% of the Remuneration value – upon transfer of manufacturing documentation confirming the manufacture of three batches of the Product;
  - 4) 10% of the Remuneration value – upon submission of the results of the performed Product stability analyses (three months after the manufacture of the Product),
  - 5) 10% of the Remuneration - upon submission of three series of the Product and the results of the Product stability analyses (six months from the manufacture of the Product).
3. The Contractor's remuneration includes:
- 1) the costs incurred for the required taxes, fees and duties with customs duties in the case of storage products imported from outside the countries belonging to the European Union
  - 2) costs of obtaining certificates, permits, licenses, approvals and other documents required by law, necessary for marketing, delivered in accordance with § 1 of the Agreement;
  - 3) costs of delivery of the Subject of the Agreement with documentation by the Contractor, including in particular: costs of securing for transportation of the Subject of the Agreement;
  - 4) all costs necessary to be incurred for the proper execution of the Contract.
4. The time limit for payment of the tranche of remuneration by the Contracting Authority shall run from the receipt of a properly issued invoice or advance invoice and shall be 30 working days for an advance invoice and 14 working days for other invoices. The invoice may be submitted in paper form to the Purchaser's address or in electronic form to [biuro@kmptm.pl](mailto:biuro@kmptm.pl) . **The basis for issuing an invoice for the implementation of a given stage is the take-over protocol, which is attached to the Agreement. In the case of an advance invoice, the delivery and acceptance protocol is not required for invoicing.**
5. The Contracting Authority hereby stipulates that payments for the performance of the Subject of the Agreement shall be made from the funds provided to the Contracting Authority in the Project. In the event that the Contracting Authority does not have the funds transferred in the Project on the date on which the due claim is due, the payment of remuneration shall be made no later than within 3 working days of their receipt by the Ordering Party.
6. The date of payment of a tranche of the Contractor's remuneration shall be the date on which the Ordering Party's bank account is debited with the amount due to the Contractor.

#### **§ 4.**

##### **Duration of the contract**

The Agreement is valid for a period of 12 months from the date of its conclusion, whereby the Contractor undertakes to:

- 1) until 30 days from the signing of the contract - transfer of the manufacturing authorization for the investigational drug product to the Ordering Party;
- 2) until 15.01.2025 - transfer / development of test methods for release of starting materials, packaging, transfer of manufacturing process with process validation, cleaning validation;
- 3) until 28.02.2025. - manufacture of three batches of the Product and transfer of documentation confirming the manufacture of three batches of the Product;
- 4) after three months from the date of manufacture - performance of stability tests under accelerated conditions in accordance with the ICH Q1A(R2) standard and submission of documents of the analyses performed (until 31.05.2025).
- 5) after six months from the date of manufacture - to perform stability tests under accelerated conditions in accordance with ICH Q1A(R2) standard, transfer documents from the analyses performed, and transfer three batches of the Product and saline (until 31.08.2025).

#### **§ 5.**

##### **Contractual penalties**

1. The following contractual penalties are established:
  - 1) for each started day of delay, in relation to the deadlines for the execution of the Agreement referred to in § 4 of the Agreement – in the amount of 0.1% of the Contractor's remuneration for each day of delay;
  - 2) in case of exceeding the deadline referred to in § 8 paragraph 4, 5 or 10 of the Agreement - in the amount of 0.1% of the Contractor's gross remuneration for each started day of delay;
  - 3) in case of violation of the obligations referred to in § 1 clause 4 of the Agreement and § 9 of the Agreement - in the amount of PLN 10,000.00 for each identified case of violation of one of the obligations, subject to item 5;
  - 4) in the event of failure to comply with the Ordering Party's comments resulting from the audit - in the amount of 0.1% of the Contractor's gross remuneration, for each started day of delay in implementing the changes in relation to the deadline resulting from the audit report;
  - 5) in the event of failure to provide the permit referred to in § 1 paragraph 2 item 4 of the Agreement - in the amount of 0.2% of the Contractor's gross remuneration, for each started day of delay;
  - 6) in the event of outsourcing the realization of any part of the Subject of the Agreement to a third party (subcontractor) without the prior consent of the Contracting Authority – in the amount of PLN 10,000.00 for each identified case;
  - 7) in the amount of 10% of the Contractor's gross remuneration referred to in § 3 item 1 of the Agreement - in the event of withdrawal from the Agreement by any of the Parties for reasons attributable to the Contractor.
2. The parties have the right to claim damages in excess of the reserved contractual penalties.
3. The Contractor agrees to deduct contractual penalties from any receivables due to him from the Contracting Authority.

## **§ 6.**

### **Amendments to the Agreement**

1. The Ordering Party provides for the possibility to amend the provisions of the Agreement to the extent necessary for its proper implementation, in particular when at least one of the following circumstances occurred:
  - 1) a change in the applicable laws affecting the Subject of the Agreement or the terms of execution of the Agreement, resulting in the inability to properly perform the Subject of the Agreement;
  - 2) there is a necessity to change the portioning of the Product - within the limits not exceeding 10% of the value of the Contractor's gross remuneration referred to in § 3 item 1 of the Agreement;
  - 3) implementation on time could not take place for reasons beyond the control of the Contractor, provided that the Contractor explains these circumstances and confirms them with appropriate documents, unless the change is requested by the Contracting Authority - in which case it is envisaged that the deadlines for implementation of the Agreement or the term of the Agreement may be changed.
2. The Contracting Authority shall allow for the possibility of changing the gross price of the Subject of the Contract, in the event of a change in the VAT rate after the conclusion of the Contract. The net price will remain unchanged. The change referred to in the first sentence will take place on the basis of an annex to the Agreement.
3. In the event that during the execution of the Agreement it becomes necessary to purchase materials in greater quantity than that indicated by the Contracting Authority in the ToR, the Contractor shall be obliged to demonstrate this circumstance to the Contracting Authority and provide the estimated number of materials necessary to purchase, together with offers confirming the purchase price. In the event that the Contracting Authority confirms that the need to purchase is due to reasons beyond the control of the Contractor, the Contracting Authority undertakes to cover the cost of purchasing

materials up to the amount resulting from the bids of material suppliers. The maximum value of changes in this regard will not exceed 10% of the Remuneration.

4. Amendments to the Agreement shall require the parties to conclude an annex to the Agreement in writing under pain of nullity.

## **§ 7.**

### **Withdrawal from the Agreement**

1. The Ordering Party may withdraw from the contract, if:
  - 1) opening of liquidation of the Contractor - within 30 days from the date of receiving information about the liquidation by the Contracting Authority;
  - 2) The Contractor will be deleted from the appropriate register - within 30 days from the date of receipt of information on deletion by the Contracting Authority;
  - 3) the delay in the implementation of any of the milestones of the Agreement referred to in § 4 will exceed 60 days - within 30 days from the date of discovery of this circumstance by the Employer;
  - 4) The Contractor violates the terms of the Confidentiality Agreement - within 30 days from the date of discovery of this circumstance by the Employer;
  - 5) in the event that the Contractor becomes aware of a change in circumstances causing the performance of the Contract not to be in the interest of the Contracting Authority, which could not have been foreseen at the time of conclusion of the Contract - within 30 days from the date of receipt of this information by the Contracting Authority;
  - 6) in the event of improper performance of the Agreement by the Contractor, including, in particular, inconsistency with generally applicable laws and Good Manufacturing Practice, despite prior request to the Contractor to perform the Agreement correctly or in accordance with the submitted audit report - within 30 days from the date specified in the request to the Contractor to cease violations;
  - 7) in the event that the Contractor loses the authorizations necessary for the execution of the Agreement, in particular the authorization to manufacture the investigated Product, or fails to obtain the authorization referred to in § 1 paragraph 4 item 2 of the Agreement or fails to submit the authorization within the prescribed period - within 30 days from the date of knowledge of this circumstance by the Ordering Party;
  - 8) in the event that the Ordering Party does not receive funds for the execution of the Agreement or a part thereof - within 14 days from the date the Contracting Authority became aware of this circumstance.
2. The withdrawal from the Agreement shall have ex tunc or ex nunc effect, at the option of the Purchaser.
3. Withdrawal from the Agreement with respect to the unperformed part of the Agreement shall not exclude or limit the right to demand payment of contractual penalties for withdrawal from the Agreement and contractual penalties for events that occurred prior to withdrawal from the Contract.
4. In the event of withdrawal from the Agreement by the Contracting Authority for reasons attributable to the Contractor, in particular those referred to in paragraph 1 items 1 - 3 and items 6 - 7, the Contractor undertakes to return to the Ordering Party the advance payment received for the Remuneration and the Remuneration received to date, no later than within 14 days from the date of receipt of the request for return.
5. In the event of cancellation or termination of the Agreement by the Contracting Authority for reasons beyond the control of the Contracting Authority, the Contractor shall not be entitled to a claim for reimbursement of the costs incurred to implement the Agreement.
- 6.

**§ 8.**

**Liability for defects (complaint)**

1. The Contractor is liable to the Contracting Authority if the assortment constituting the subject matter of the Agreement has defects that reduce its value or usefulness in view of the purpose specified in the Agreement or resulting from the purpose of the thing, or if the supplied assortment constituting the subject matter of the Agreement does not have the properties it should have or was issued in an incomplete state.
2. The rights under this paragraph shall be vested in the Contracting Authority for a period of 3 months from the date of signing the acceptance protocol, separately for each batch of Product.
3. The Contracting Authority shall submit complaints via e-mail to the following e-mail address:  
.....
4. The Contractor shall be obliged to respond to the complaint submitted by the Contracting Authority no later than within 14 days from the date of its submission to the Contracting Authority at the e-mail address indicated in paragraph 3.
5. The Contractor, within the scope of a complaint submitted by the Ord Contracting Authority, undertakes to:
  - 1) supplement the missing quantity of the Product - in case the complaint concerns quantity shortages;
  - 2) manufacture and deliver at its own expense a defect-free series or part of a series of the Product in exchange for the part in which defects have been found - if the complaint concerns quality defects,within the period established by the Purchaser, not exceeding 210 days from the date of receipt of the complaint.
6. The Contracting Authority is entitled to file a complaint in particular:
  - 1) to the extent of the analyses performed by the Contractor (confirmed by certificates) - in this case, the Ordering Party shall verify the compliance of the submitted certificates with the specifications presented to the Contractor, and any discrepancy shall be qualified as a complaintable defect, unless the Contractor demonstrates that the discrepancy is not due to improper execution of the Agreement;
  - 2) to the extent resulting from improper transportation of the Product series - in the event that the Product received was not delivered in the expected condition (e.g., spillage, damage to transport containers).
7. In the event that quantitative or qualitative defects are found by the Contracting Authority upon acceptance of the Product series, including defects in the transportation of the Subject of the Agreement, it shall be entitled to refuse acceptance of the Product series. In this case, the Contractor shall be in default.
8. In the event that a dispute arises between the Parties as to the validity of the complaint, the examination of the complaint shall be commissioned to an independent third party selected by both Parties. The initial cost associated with the commissioning of the examination shall be borne by the Parties in equal parts, with the Party whose position proves to be unfounded as a result of the examination reimbursing the other Party for the costs incurred by it.
9. In the event that the Contractor fails to perform the Product stability tests by August 31, 2025, the Ordering Party shall be entitled to commission a third party at the Contractor's expense and risk (substitute performance), without calling for performance of the Agreement. The parties agree that any costs incurred by the Contracting Authority in connection with the substitute performance may be deducted by the Ordering Party from the Contractor's remuneration without prior call for payment, to which the Contractor agrees.
10. The Ordering Party shall also be entitled to lodge complaints regarding the documentation provided by the Contractor. In the event of a complaint in this regard by the Contracting Authority, the Contractor undertakes to provide properly prepared documentation or to provide missing documentation (depending on the type of defect), no later than within 7 working days from the date

of receipt of the complaint.

#### **§ 9.**

##### **Audit**

1. As part of the Contractor's supervision, the Contractor, during the term of the Agreement, agrees to be audited by the Contracting Authority to assess the compliance of the manufacture of the Product with generally applicable laws and the terms of the Agreement, in particular with regard to:
  - 1) records of receipt and storage of raw materials used for production, together with their quality certificates;
  - 2) protocols for carrying out the various stages of production;
  - 3) analysis reports with raw data.
2. The Contracting Authority will inform the Contractor of its intention to conduct an audit no later than 7 days before the planned audit date.
3. As part of the audit, the Contractor agrees to provide the Contracting Authority's representatives with access to all premises where processes related to the manufacturing of the Product take place and to all documentation related to the Product. The audit will be concluded with a written report prepared by the Contracting Authority, which will be provided to the Contractor.
4. The Contractor shall rectify any irregularities identified by the Contracting Authority in connection with the execution of the audit, within the period indicated in the report referred to in paragraph 4.

#### **§ 9.**

##### **Assignment of receivables and the right to set-off**

The Contractor is not entitled to transfer the rights and obligations under the Agreement without obtaining the consent of the other Party in writing (under pain of nullity), or settling the obligations by compensation.

#### **§ 10.**

##### **Final Provisions**

1. The Contractor undertakes to keep confidential all information obtained in connection with the execution of this Agreement, under the terms of the Confidentiality Agreement *constituting Appendix No. 7 to the Agreement/concluded by the Parties on....*<sup>3</sup>
2. Any disputes arising from the implementation of this contract will be settled in the court competent for the seat of the Contracting Authority.
3. The Agreement has been drawn up in duplicate, one for each Party.
4. In matters not covered by the provisions of the Agreement, generally applicable provisions will apply, in particular the provisions of the Act of 23 April 1964 - Civil Code.

**Contractor:**

**Ordering Party:**

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<sup>3</sup> Depending on whether the Parties have entered into a confidentiality agreement at the stage of conducting the public procurement proceedings.

Appendix to the Agreement

Zabrze, date .....

**DELIVERY AND ACCEPTANCE REPORT**

<b>Transferring</b>		<b>Receiving</b>	
		<b>Silesian Park of Medical Technology Kardio-Med Silesia sp. z o.o.</b> 10c M. C. Skłodowskiej Street, 41-800 Zabrze	
<b>Agreement Number</b>			
<b>Transferring person</b>			
<b>Date</b>			
<b>No.</b>	<b>Name of the subject of the order</b>	<b>LOT number (if applicable)</b>	<b>Number of vials, packages / documentation provided / other</b>
1.			
2.			
3.			
4.			
<b>Transport temperature (if applicable): .....</b> <b>Correct: <input type="checkbox"/> TAK <input type="checkbox"/> NIE (Mark the appropriate)</b>			
<b>Actions performed (comments) / documentation provided</b>			
<b>Stamp and signature of the person delivering</b>		<b>Stamp and signature of the receiving party</b>	

No	Name	Unit price	VAT rate	Gross value
1	Manufacture of three batches of the Product (nanotherapeutic) in the amount of 3000 ml (delivered in three series - 3 x 1000 ml) in 5 ml packs and NaCl saline in 5 ml packs, together with the documentation required by the Ordering party.			

Detailed description of the activities performed:

No.	Features of the subject of the contract	Limiting parameter	Offered parameter
1.	Exemption of starting and packaging materials for production based on Ph.Eur. compliance.	YES	
	Verification and validation of analytical methods for compliance with Ph.Eur.	YES	
	Analysis of raw material for production	YES	
	Analysis of auxiliary substances	YES	
	Audit at substance suppliers	YES	
2.	Scalability of the manufacturing process and development of the necessary documentation	YES	
3.	Manufacture of investigational drug product, including: - process validation - cleaning validation - bottling, packaging, labeling, blanking	YES	

4.	Series release, including specification compliance analysis and stability testing at 3 and 6 months after the manufacture of a batch of the Product, at three time points.	TAK	
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.....  
Signature of Contractor

**List of completed services**  
**/meeting the requirements of the terms of reference/.**

completed within the last three years before the deadline for submission of tenders, and if the period of activity is shorter - in this period, the execution of at least three implementations consisting in: manufacture of medicinal products in liposome manufacturing technology in GMP standard and/or realization of medicinal products in non-sterile or sterile liquid form with a total value of at least PLN 1 million net.

The condition is considered fulfilled if the Contractor confirms the implementation with relevant documents (Invoices, references or other supporting documents with a description of the subject of the contract). In the event that the above were not carried out on behalf of an external entity, the Contractor should provide documents confirming the manufacture of products for their own use and/or marketing.

No.	Description of the completed service	Recipient's name	Date of service delivery

.....  
Date

.....  
Signature of Contrator

**List of the personnel who will perform the contract  
and/or participating in the performance of the contract**

<b>Feature</b>	<b>Names and surnames of persons who will perform the contract and/or will participate in the execution of the contract</b>	<b>Scope of activities performed and legal requirements for the function performed</b>	<b>Description of your professional qualifications and education, seniority in the position, with documented position, experience and qualifications and their confirmation (e.g. diplomas, employment contracts with the position shown).</b>
<b>Quality Department personnel</b>		<b>In accordance with the requirements of Section 2.3 "Quality Management" of Appendix No. 3 of the Decree of November 9, 2015 on the requirements of Good Manufacturing Practice (as amended).</b>	
<b>Production Department Personnel</b>		<b>In accordance with the requirements of Section 2.3 "Quality Management" of Appendix No. 3 of the Decree of November 9, 2015 on the requirements of Good Manufacturing Practice (as amended).</b>	
<b>Qualified Person</b>		<b>In accordance with the provisions of Article 48 of the Law of September 6, 2001. Pharmaceutical Law (as amended).</b>	

.....  
Date

.....  
Signature of Contractor

.....  
Contractor's stamp

**STATEMENT**

Submitting a tender in the procedure for the procurement of „Contractor selection for contract manufacturing of a GMP-standard investigational medicinal product based on liposome technology for use in a Phase I clinical trial, with the required documentation” (15/Z/24)

We declare that the person(s) indicated in Appendix 6:

- name, surname .....

has/have the authorizations required by the provisions of Chapter V of the Terms of Reference.

.....  
date

.....  
Signature of Contractor

Persons should be made aware of the information obligation:

In accordance with Articles 13 and 14 of the Regulation (EU) 2016/679 of the European Parliament and of the Council of April 27, 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data and repealing Directive 95/46/EC (RODO), we inform you that:

1. the administrator of your personal data is Silesian Park of Medical Technology Kardio-Med Silesia, 10C M. Curie-Skłodowskiej Street, 41-800 Zabrze (KRS:0000396540, NIP:6482761515, Regon:242742607).
2. We have appointed a Data Protection Officer in the person of Mr. Gabriel Kolasa for information regarding your personal data, please contact the Data Protection Officer's e-mail box: [iod@kmptm.pl](mailto:iod@kmptm.pl).
3. your personal data will be processed in order to:
  - a) establishing business relations including signing contracts or for the purpose of contact in connection with the execution of a contract on the basis of Article 6(1)(f) of the RODO
  - b) asserting and defending against claims on the basis of Article 6(1)(f) RODO
  - c) fulfillment of legal obligations incumbent on the administrator related to, for example, financial and accounting settlement on the basis of Article 6(1)(c) RODO;

4. your personal data will be forwarded to law firms, software providers, e-mail box host, IT support and software maintenance company, courier companies, Poczta Polska S.A., auditors, document archiving company, consulting company, banks, the tax office and other entities when required by law.
5. Your personal data will not be transferred to third countries.
6. Your personal data will be processed for the duration of the proceedings or execution of the contract, as well as until the statute of limitations for claims arising therefrom. Data from financial documents will be processed for the time resulting from the law on accounting.
7. You have the right of access to the content of your data and the right to rectify, restrict processing, delete data and object.
8. we have obtained your data:
  - in case you are a person representing a company - from the entity in which you serve as a member of the bodies of legal entities and from the KRS,
  - in case you are a person appointed by the entity to contact: from the entity in which you perform this function within the scope of the contract being executed.
9. You have the right to lodge a complaint to the President of the Office for Personal Data Protection (ul. Stawki 2, 00-193 Warsaw), if you consider that the processing of personal data violates the law.
10. your data will not be subject to profiling and automated decisions will not be made on their basis.



Appendix no. 7  
do Proceeding no. 15/Z/24

## CONFIDENTIALY AGREEMENT

concluded on ..... 2024 r. in Zabrze<sup>4</sup> between:

**Silesian Park of Medical Technology Kardio-Med Silesia Ltd.**

with headquarters in Zabrze, ul. M. Curie- Skłodowskiej 10c, registered in the Register of Entrepreneurs of the National Court Register kept by the District Court in Gliwice, 10th Commercial Division of the National Court Register under the number KRS 0000396540, NIP 648-276-15-15, REGON 242742607, hereinafter referred to as the "Ordering Party", represented by:  
Adam Konka - President of the Management Board

hereinafter referred to in the body of the Agreement as the "**Disclosing Party**"

(in the case of an entrepreneur entered in the National Court Register)

(name) ....., the registered office in..... Street, NIP: .....,  
REGON: ....., share capital: ..... entered into the Register of Entrepreneurs kept by the District Court ..... under KRS number: ..... , represented by:

.....

(in the case of an entrepreneur entered in CEIDG)

(name and surname) ....., residing in ..... PESEL: ..... an entrepreneur running a business under the name of ..... based in ... .. at ..... Street, NIP: ..... ,  
REGON: ..... ,

hereinafter referred to in the body of the Agreement as the "**Receiving Party**"

hereinafter also referred to separately as "**Party**" or jointly as "**Parties**", with the following content:

### § 1.

1. Whenever **Confidential Information** is referred to in this Agreement, it shall mean all information about the Disclosing Party and its business and the medicinal product being manufactured as part of the procurement procedure for "**Contractor selection for contract manufacturing of a GMP-standard investigational medicinal product based on liposome technology for use in a Phase I clinical trial, with the required documentation**" No. 15/Z/24, in particular, general information, technical

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<sup>4</sup> If the Parties sign the agreement with an electronic signature, the date of conclusion will be the date of the last qualified signature by the Parties.

information, technological information, intellectual property, such as. existing patents and patent applications, organizational information, including information about cooperating individuals and institutions/companies, financial, legal or other information of economic value, as well as information obtained as a result of analysis or processing of the information provided, regardless of the manner of disclosure, transmitted in writing, orally, electronically or by any other means, regardless of the form and manner of expression and the degree of elaboration. Confidential Information shall also include any non-public or undisclosed data regarding third parties and their activities relevant to the outcome of this Agreement. If there is any doubt as to the qualification of certain information for the purposes of the performance of this Agreement, it shall be presumed to be Confidential Information.

## **§ 2.**

1. The Receiving Party agrees to keep Confidential Information obtained during the term of this Agreement confidential indefinitely from the moment of its conclusion.
2. The Parties may terminate the Agreement without a notice period, in which case all Confidential Information received by the Receiving Party must be destroyed and may not be used for any purpose. Termination of the Agreement shall not deprive the Disclosing Party of the possibility of claiming the contractual penalty referred to in § 2 Paragraph 8 of the Agreement and the obligation to compensate for damages, in particular in the event that the Confidential Information is not destroyed by the Receiving Party or is used for any purpose after termination of the Agreement.
3. The obligations set forth in Paragraph 1 shall not apply with respect to Confidential Information or any part thereof which:
  - 1) are published, generally known and made public without violating the provisions of this Agreement,
  - 2) have been lawfully transferred by a third party without violating any non-disclosure obligations to the Parties, including those set forth in this Agreement,
  - 3) have been disclosed with the prior written consent of the Disclosing Party,
  - 4) have been disclosed to the competent public authorities or local governments, due to the content of mandatory legal regulations,
  - 5) have been completely independently developed by the Receiving Party.
4. The Receiving Party shall keep the Confidential Information confidential, and in particular shall take the same precautions and the same security measures with respect to the Confidential Information as those used by the Transferring Party with respect to its own Confidential Information and for which the Receiving Party warrants that it will provide adequate protection against unauthorized disclosure, copying or use.
5. The Receiving Party of the Confidential Information, undertakes to receive the Confidential Information and to transfer it only through the persons notified of the obligations under this Agreement.
6. the Party Receiving Confidential Information undertakes not to disclose the Confidential Information received from the Disclosing Party either in whole or in part to third parties, as well as not to use the Confidential Information for any material benefit. Disclosure to third parties, may be made only on the condition that, in each such case, the Party receiving the Confidential Information, obtains the written consent of the Disclosing Party and assures in writing that the provisions of this Agreement will be complied with by such persons.
7. The Disclosing Party shall provide the Receiving Party with Confidential Information, in connection therewith:

- 1) at any time, upon the Disclosing Party's request, the Receiving Party shall return to the Transferring Party all Confidential Information (and all copies and extracts thereof) or destroy all written Confidential Information (and all copies and extracts thereof). The destruction of the Confidential Information shall be certified in writing by the Receiving Party;
  - 2) the Receiving Party agrees that it will not, without the prior written consent of the Disclosing Party, make any public announcement, public statement, or any other disclosure to any person (except as permitted hereunder or required herein) regarding the fact that any Confidential Information has been released or that discussions or negotiations are taking place regarding a potential transaction involving the Disclosing Party.
8. The Receiving Party agrees to pay to the Disclosing Party a contractual penalty in the amount of PLN 20,000.00 for each violation of the terms of this Agreement.
  9. The Disclosing Party shall be entitled to recover damages on general terms in the event that the Receiving Party breaches its obligations under this Agreement and the value of damages resulting from the breach exceeds the amount of the contractual penalty charged.

**§ 3.**

1. Amendments to the Agreement shall require a written annex for its effectiveness.
2. In matters not covered by this Agreement, the provisions of generally applicable law, in particular the Civil Code, shall apply.
3. The Agreement has been drawn up in two counterparts, one for each Party.

**Disclosing Party**

**Receiving Party**

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